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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,382	04/09/2001	H. Robert Masure	600-1-158N DIV	4666

23565 7590 10/28/2003

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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/28/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,382

Applicant(s)

MASURE ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18, 28, 33-46, 48-54 and 62-72 is/are pending in the application.
- 4a) Of the above claim(s) 13-18, 28, 33-40 and 63-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 48-54 is/are allowed.
- 6) ☐ Claim(s) 41-46, 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Claims 13-18, 28, 33-40, 63-72 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6.

Rejections withdrawn

The rejections under 35 USC 112 and the claim objections are rendered moot by the amendments to the claims. The rejections of claim 62 under 35 USC 102(e) or (a) over Briles et al 6,500,613 or WO 97/09994, are withdrawn in response to the amendment to the claim.

Claim Rejections - 35 USC § 112

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is indefinite for several reasons. In line 2, "the nucleotide" lacks antecedent (line 1 uses "oligonucleotide"). The claim recites "capable of hybridizing" but does not specify hybridization conditions; since different oligos will hybridize under different conditions, this affects the scope of the claimed molecules. Finally, the claim recites "hybridizing with the nucleic acid encoding an amino acid of..." Is one codon intended? Would this language better describe the intended product?:

An oligonucleotide capable of screening for a nucleic acid encoding a streptococcal choline binding protein, wherein the oligonucleotide or its complement encodes at least 5 contiguous amino acids of SEQ ID NO:1 or SEQ ID NO:9.

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The limitation of 5 contiguous amino acids is supported by the disclosure of an oligonucleotide of 15 or more nucleotides at page 30, line 17.

Claim 62 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:24, does not reasonably provide enablement for "substantially homologous" nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On specification page 32, lines 11-3, applicant explicitly defines "substantially homologous" as matching at least about 75 % over the length of a DNA sequence. Claim 62 therefore is drawn to a nucleic acid at least about 75% homologous to SEQ ID NO:24. The specification does not teach the properties of nucleic acids that are up to 25% divergent from SEQ ID NO:24, and does not teach how to use the divergent nucleic acids. Considering the absence of teaching commensurate in scope with the claimed subject matter, it is concluded that undue experimentation would be required to use the full scope of the claimed nucleic acids.

Claim Rejections - 35 USC § 102

Claims 41-45 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Briles et al 6,500,613.

Claims 41-45 and 62 are rejected under 35 U.S.C. 102(a) as being anticipated by Briles et al WO 97/09994.

As discussed in the previous Office action, the effective date of claims 41-45 and 62 is May 1, 1997, because prior to this date there was not an adequate written

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description of the nucleic acid of these claims. Both Briles patents teach a streptococcal binding protein which comprises SEQ ID NO:9, see Figure 21, residues 374-385.

Applicants argue that the nucleic acids as claimed are described in the provisional application 60/016,632, and point to page and line providing literal support for part or all of the claim language. However, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Fiers v. Revel*, 25 USPQ2d 1601, 1606, quoted in *University of California v. Eli Lilly and Co.* (CA FC) 43 USPQ2d 1398, 1404. The provisional application contains a statement that the subject matter now claimed is part of the invention, and refers to a potential method for isolating the nucleic acids now claimed. However, the provisional application reasonably conveys possession of only fragmentary nucleotide sequences. Therefore, the nucleic acids of claims 41-45, which encompass full length coding sequences, are not supported by an adequate written description in the provisional application.

Allowable Subject Matter

Claims 48-54 remain allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

10/27/03


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1880 / 600